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March 29, 2022

VIA ECF

The Honorable Robert B. Kugler
United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets Room 1050
Camden, NJ 08101

Special Master the Honorable Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower
18th Floor
Philadelphia, PA 19103

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Special Master Vanaskie:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on March 30, 2022. The parties do not expect the need to discuss any confidential materials as part of these agenda items.

1. Outstanding Request for Production of Valsartan Testing Documents from Plaintiffs' Expert Ron Najafi

Dr. Ron Najafi has been disclosed by Plaintiffs as a class expert. He offers the opinion generic valsartan-containing medications that contained NDMA or NDEA at any level were not the "equivalent of" Novartis's reference listed drugs, Diovan or Exforge. (ECF No. 1748-3, Najafi Rep. ¶ 34.) Dr. Najafi assumed for purposes of his report that the Novartis products did not contain NDMA or NDEA at any level above zero. (Najafi Dep. Tr. 139:24–140:7.)



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During the course of Dr. Najafi's deposition, Defendants learned Dr. Najafi and his laboratory, Emery Pharma, conducted testing in connection with a citizen petition submitted to FDA on June 13, 2019, by Valisure LLC. (Najafi Dep. Tr. 141:17-142:2 [stating with "[o]ne hundred percent certainty" that Emery validated the testing performed by Valisure in connection with the citizen petition].) The Valisure citizen petition reflected testing for NDMA and an allegedly carcinogenic solvent, N,N-Dimethylformamide ("DMF"), performed on various manufacturers' valsartan-containing medications, including Novartis product. (*See* Ex. A, Valisure Citizen Petition, at Appendix A.) Dr. Najafi confirmed that his lab "repeated Valisure's work" by testing "the same pills that [Valisure] tested" to confirm Valisure's results were "in the ballpark" of the levels detected by Emery. (Najafi Dep. Tr. 142:3-143:11.) Ultimately, Dr. Najafi was able to "corroborate" the nitrosamine data included in the Valisure citizen petition. (*Id.*)

The Valisure citizen petition showed detectable levels of NDMA in the majority of Novartis product tested, including a level of 17 nanograms in a 40 mg tablet. (Valisure Citizen Petition, at Appendix A, attached as Exhibit A.) These data directly contradict the assumption underlying Dr. Najafi's opinion—i.e., that Novartis product did not contain nitrosamine impurities at any level above zero. Defendants' notice of deposition had requested the production of any testing data and communications with third parties concerning nitrosamines in valsartan in Dr. Najafi's possession, custody, or control, but no documents were produced in response. (*See* ECF No. 1890, Najafi Not. of Dep.)

When confronted with the citizen petition at his deposition, Dr. Najafi backtracked from his prior, unequivocal testimony that his lab corroborated the nitrosamine levels reflected in the



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Valisure citizen petition. During re-direct by Plaintiffs' counsel, Dr. Najafi suggested that, because Emery Pharma is not identified in the citizen petition, his lab actually was not involved in any testing of product from Valisure. (Najafi Dep. Tr. 223:7-22.)

In the hope of settling the matter, Defendants followed up by letter on February 16, 2022, requesting production of documents reflecting any testing, methods, protocols, and procedures performed by Dr. Najafi or his lab on any valsartan-containing medications, as well as communications concerning the Valisure citizen petition. (*See* Defs.' 2/16/22 Letter, attached as Exhibit B.) These data and related documents and communications are plainly relevant to class certification. First, the information bears on the two core assumptions underpinning Dr. Najafi's opinions—namely, that (i) all of the Defendants' generic valsartan contained nitrosamine impurities at some level above zero, and (ii) none of the Novartis product contained nitrosamines at any level. Even more broadly, testing demonstrating the presence or absence of nitrosamine impurities in the Defendants' valsartan goes to central questions at issue at the Rule 23 stage, particularly in light of Plaintiffs' theory regarding "Lifetime Cumulative Thresholds" and the value of Defendants' medication.

Plaintiffs submitted a response on February 25, 2022. (*See* Pls.' 2/25/22 Letter, attached as Exhibit C.) They took the position that Defendants' request for production of testing data was not "supported by the record," despite Dr. Najafi's unequivocal testimony that his lab had, in fact, conducted testing in support of the Valisure citizen petition. Plaintiffs suggested that further meet and confer would be helpful.

The parties met and conferred by telephone on March 8 and then again on March 11. During those discussions, Defendants directed Plaintiffs' counsel to the portions of Dr. Najafi's



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deposition supporting the notion that Emery Pharma had, in fact, tested valsartan-containing medications. Recognizing, however, the ambiguity created by subsequent testimony, Defendants asked Plaintiffs to confirm one way or the other whether Dr. Najafi or his lab is in possession, custody, or control of any testing data or communications concerning the levels of nitrosamine impurities, if any, in valsartan API or finished-dose products. Plaintiffs committed to providing a response to this foundational question. Having not received any further substantive communications from Plaintiffs, Defendants followed up by email on March 22 and again on March 25. At that time, Plaintiffs suggested a response would be received by March 28. (*See* 3/25/22 Email Chain, attached as Exhibit D.)

On March 29—the day the parties’ agenda statements are due to be filed in advance of the March 30th Case Management Conference—Plaintiffs served their supplemental response.¹ Plaintiffs now acknowledge that Dr. Najafi did, indeed, conduct testing on valsartan provided by Valisure in connection with the citizen petition. Plaintiffs suggest that the samples from Valisure were “blinded,” which Defendants interpret to mean Valisure did not reveal the manufacturer of the drug to be tested by Emery Pharma. Nonetheless, Plaintiffs surmise that none of the testing was performed on product manufactured by Novartis or the Defendants. The basis for this conclusion is nothing more than Dr. Najafi’s comparison of the results of testing performed by his lab to the data set forth in the Valisure citizen petition. More specifically, because apparently none of the levels of NDMA and DMF measured by Dr. Najafi’s lab was an exact match to the levels

¹ Plaintiffs have marked the letter Highly Confidential so, out of respect of that designation but without waiver of any potential challenges to that designation, Defendants will not attach it as an exhibit at this time.



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of NDMA and DMF reflected in the citizen petition, Dr. Najafi “advises” that he does not believe his testing was performed on Novartis’s or Defendants’ product.

Because Defendants did not receive Plaintiffs’ supplemental response until a few hours before the filing of this agenda statement and there appears to be an opportunity to continue the meet-and-confer process, Defendants do not yet believe the dispute is ripe for resolution by the Court. However, Defendants wanted to apprise the Court of the background of the dispute and flag the issue should it require the Court’s attention at a later date.

2. Pending Motion for Clarification

Defendants have moved for clarification regarding Daubert Hearing Order 1, ECF No. 1958. (*See generally* ECF No. 1976, Defs.’ Mot.; ECF No. 1976-1, Defs.’ Br.) Defendants seek confirmation that Dr. Lagana and Dr. Hecht will not be permitted to offer the opinion trace levels of NDEA potentially detected in Defendants’ valsartan-containing medications can cause any particular type of cancer at issue in this litigation. Plaintiffs have not yet responded to the motion. Defendants, however, would be pleased to address any questions the Court may have at this time.

3. Unopposed Request for Extension of Class Certification Briefing Deadlines

Defendants are seeking a seven-day extension of the deadline by which to submit their opposition briefs in response to Plaintiffs’ motions for class certification, which currently falls on April 5, 2022. (ECF Nos. 1747, 1748, 1749, 1750). Plaintiffs do not oppose this request as long as Plaintiffs also receive an additional week in which to submit their replies in support of class certification. (*See* Email from A. Slater to R. Bernardo, Mar. 23, 2022, attached as Exhibit E).

Defendants seek this extension because the ZHP Defendants are in the process of changing counsel in this litigation. Duane Morris will be withdrawing at the end of the week, and Skadden,



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Arps, Slate, Meagher & Flom (“Skadden”) will be replacing Duane Morris in the litigation. As the Court is aware, the litigation has a lengthy history, and the Skadden attorneys have been working hard to get up to speed on the legal and factual issues central to the litigation as swiftly as possible. In order for Skadden to provide meaningful legal representation in connection with responding to Plaintiffs’ class proposals, however, a brief, seven-day extension of the deadline for Defendants to file their responses to Plaintiffs’ motions for class certification is required. Accordingly, Defendants ask that the Court grant a seven-day extension of the remaining briefing deadlines as to Plaintiffs’ motions for class certification, with Defendants’ oppositions due on April 12, 2022, and Plaintiffs’ reply briefs due on May 10, 2022.

4. Plaintiff Fact Sheet Deficiencies and Orders to Show Cause

Cases Addressed at the February 28, 2022 Case Management Conference:

The Court has issued six show cause orders returnable at the March 30, 2022 Case Management Conference:

- *Charlene Mills v. Actavis, et al.* – 21-cv-13611
- *Jimmie Thorn v. Mylan, et al.*, – 20-cv-20603
- *Martin Scott v. ZHP, et al.*, – 21-cv-17216
- *Tracy Whitfield v. ZHP, et al.*, – 21-cv-15076
- *Deborah Harris v. Aurobindo, et al.*, – 20-cv-19164
- *Ernestine Williams v. Mylan, et al.*, – 21-cv-06946

The issues in the *Williams* matter are resolved, and the show cause order may be withdrawn.

The issues in the *Mills* and *Thorn* matters remain unresolved, but the parties are working towards a resolution and request a one-month extension of these orders to show cause until the April 27, 2022 Case Management Conference.



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The issues in *Scott*, *Whitfield*, and *Harris* remain unresolved, and Defendants accordingly move for dismissal of these three matters at this time.

Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases were previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs’ leadership on March 23, 2022, and a global meet and confer was held on March 25, 2022. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the March 30, 2022 Case Management Conference:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	James Larsen v. Actavis, et al.	21-cv- 18313	Newlands and Clark	Need medical expenses	12/28/2021
2.	Estate of William Byrnes v. Aurobindo, et al	21-cv- 13325	Stark & Stark	Need usage dates; need cancer diagnosis information; need medical expenses; authorizations must be made out to providers listed in PFS, not a template.	2/5/2022



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3.	Deborah Harris – Estate of Donald Harris v. Aurobindo Pharma, Ltd., et al	21 - CV- 06395	Arnold & Itkin, LLP	No authorizations, Incomplete PFS, no NDC codes or identification that recalled product was consumed	01/25/2022
4.	Estate of Sloan Mitchell v. Aurobindo	21- CV- 20355	Watts Guerra	No authorizations for Dr. Michael Gainey and Dixie Stone PA-C No Medical expenses	02/11/2022
5.	Jeffrey S. Williams v. Aurobindo Pharma	21-cv- 16345	Heninger Garrison Davis LLC	Failure to provide medical expense records and list of healthcare providers	1/20/2022
6.	Kelly Donaldson v. Aurobindo Pharma	21-cv- 18272	Newlands and Clark	Failure to provide dates of taking Valsartan; failure to list dates she was treated by doctors	12/29/2021
7.	Eric Thompson	21-cv- 19973	Levin Papantonio	No PFS Filed.	1/12/22
8.	John McDermott	21-cv- 20426	Levin Papantonio	No PFS Filed.	2/9/22
9.	Chadwick Wilson	21-cv- 20624	Morgan & Morgan	No PFS Filed.	2/21/22

First Listing Cases – Remaining Core Deficiencies:

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved.

This list was provided to Plaintiff leadership on March 23, 2022 and a global meet and confer was held on March 25, 2022. Defendants have also been available for further discussion as needed.

This is the first time these cases have been listed on an agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.



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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Michael Keicher v. Aurobindo Pharma, et. Al.	21-cv-20760	Honik LLC	Need medical expenses; Teva is not an API manufacturer; No medical records; Provide NDC codes listed in pharmacy records.	2/18/22
2.	Robert Sanford v. Aurobindo Pharma Ltd. et al.	21-cv-20674	Levin Papantonio Rafferty	Need medical expenses; amended PFS needs to be uploaded	3/2/22
3.	Henry Parker, Jr. v. Hetero Drugs, Ltd., et al	21-cv-19401	Levin Papantonio	III.G.a-III.G.c – Failed to provide any substantive responses to identify Plaintiff’s claimed medical expenses, including: the name of the healthcare provider for each claimed medical expense; the date of service for each claimed medical expense; and the monetary amount of each claimed medical expense. XI.B.2 – No pharmacy records were produced for Liddy’s Health Mart Pharmacy. Also, no medical records were produced for the identified physicians who prescribed Valsartan to Plaintiff, being: Ali Crawford and Phyllis Wright. XI.B.18 – No billing records produced.	2/18/22
4.	Matt Jolissaint v. Mylan, et. al	2021 - CV-19769	Honik LLC	Please provide medical records	2/16/22



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5.	Carl Huston v. Aurobindo Pharma Ltd., et al	21-cv-20758	Honik LLC	-Failed to attach records demonstrating alleged injury	2/22/2022
6.	Jeffery Johnson v. ZHP, et al.	21-cv-20353	Meshbeshier & Spence Ltd.	-Failed to provide authorizations for Fillmore County insurance provider	2/23/2022
7.	Ulysses Payne v. ZHP et al.	21-cv-00495	Serious Injury Law Group	-Failed to address numerous deficiencies listed in Deficiency Notice	3/8/2022
8.	Dexter Turner v. ZHP	22-cv-00004	Morgan & Morgan	No PFS Filed.	PFS Due - 3/3/22
9.	Nancy Mastbergen v. Hetero	22-cv-00038	Oliver Law Group	No PFS Filed.	PFS Due - 3/5/22
10.	Mario Sherber v. ZHP	22-cv-00208	Morgan & Morgan	No PFS Filed.	PFS Due - 3/17/22
11.	Robert Brown	21-cv-13857	Serious Injury Law Group	No PFS Filed.	PFS Due - 3/20/22
12.	Daniel Given v. Torrent	21-cv-20286	Serious Injury Law Group	No PFS Filed.	PFS Due - 3/20/22
13.	Dinah Brown v. Camber	21-cv-14477	Serious Injury Law Group	No PFS Filed.	PFS Due - 3/20/22
14.	Betty Hall v. Torrent	21-cv-20447	Serious Injury Law Group	No PFS Filed.	PFS Due - 3/24/22
15.	Annie Pace v. Major	20-cv-19170	Serious Injury Law Group	No PFS Filed.	PFS Due - 3/24/22



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16.	Marion Dennis v. Solco	20-cv-11163	Serious Injury Law Group	No PFS Filed.	PFS Due - 3/24/22
17.	Elie Greene v. Aurobindo	21-cv-03214	Serious Injury Law Group	No PFS Filed.	PFS Due - 3/24/22
18.	Linda Palmer v. Aurobindo	22-cv-00429	Levin Papantonio	No PFS Filed.	PFS Due - 3/28/22
19.	Vincent Anderson v. ZHP	22-cv-00449	Levin Papantonio	No PFS Filed.	PFS Due - 3/28/22
20.	Kerry Jackson, Individually and O/B/O E.O Janice Jackson v. Hetero Drugs, Ltd., et al	22-cv-00154	Hollis Law Firm, P.A.	No PFS Filed	PFS Due - 3/13/22

5. Withdrawal of Duane Morris

On March 31, 2022, or very shortly thereafter, the attorneys from Duane Morris LLP who are counsel of record for the four ZHP Parties in the MDL and related cases will be moving to withdraw their appearances in those matters. The ZHP Parties will be continued to be represented in those matters by Skadden, Arps, Slate, Meager & Flom LLP. As after the withdrawal of their appearances Seth Goldberg and Jessica Priselac will no longer be serving as Defense Liaison Counsel, and Seth Goldberg also will no longer be a member of the Defendants' Executive Committee, Defendants consent to the Court's appointment of Jessica Miller of the Skadden firm to serve in those roles.



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Respectfully submitted,

/s/ Lori G. Cohen

Lori G. Cohen

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)
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